Remarks

Claims 1, 3 and 26 are amended herein. Thus, claims 1, 3-4, 11, 13-14, 26-29 and 34-35 are pending in this application.

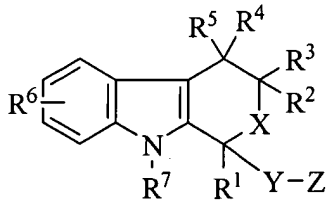
Support for the amendment to claims 1 and 26 can be found in the instant specification, for example, in Example 5 and Figure 9-10. The amendments to the claims are intended to clarify Applicant's invention and are not intended to limit the equivalents to which any claim element may be entitled.

The 35 U.S.C. §103(a) Rejections

The Examiner rejected claims 1, 3-4, 13 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Rephaeli (U.S. Patent No. 5,939,455). The Examiner rejected claims 11, 14, 26-28 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Rephaeli (U.S. Patent No. 5,939,455) in view of WO 98/09603. Applicant respectfully traverses these rejections.

Applicant respectfully submits that the Office Action has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the reference(s) must teach or suggest all the claim limitations. MPEP § 2143. See also *In re Rouffet*, 47 U.S.P.Q.2d 1453. The court in *Rouffet* stated that "even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill that suggests the claimed combination." *Rouffet* at 1459. Further, even if the allegation of obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of the single reference. *B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp.*, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996).

Claim 1, as amended, recites "[a] method to treat multiple myeloma in a mammal, said method comprising contacting mammalian cancer cells with an amount of a compound of formula (I):



(I)

wherein R^1 is lower alkyl, lower alkenyl, lower alkynyl, lower cycloalkyl, phenyl or benzyl, R^2, R^3, R^4 and R^5 are the same or different and are each hydrogen or lower alkyl; R^6 is hydrogen, lower alkyl, hydroxy, lower alkoxy, benzyloxy, lower alkanoyloxy, nitro or halo, R^7 is hydrogen, lower alkyl or lower alkenyl; X is oxy; Y is carbonyl or $(C_1$-$C_3)$alkyl(CO), wherein each alkyl is substituted with 0-2 $(C_1$-$C_4)$ alkyl, and Z is hydroxy, lower alkoxy, amino, lower alkylamino, di(lower)alkylamino or phenylamino, or a pharmaceutically acceptable salt thereof, effective to kill cancerous bone marrow cells and to achieve a plasma level of the compound in the mammal of about 250 μM to about 800 μM."

Claim 26 as amended recites "[a] method of treating multiple myeloma comprising administering to a human patient afflicted therewith an amount of 1-R-(-) etodolac effective to achieve a plasma level of the compound in the human patient of about 250 μM to about 800 μM, and to kill cancerous multiple myeloma cells, while maintaining the viability of normal bone marrow cells."

It is respectfully submitted that all of the claims recite a method to treat multiple myeloma wherein mammalian cancer cells are contacted with an amount of a compound of formula (I), e.g., etodolac or anolog, or 1-R-(-) etodolac that is per se effective to kill cancer cells. This is not disclosed or suggested by Rephaeli or WO 98/09603.

Additionally, it is respectfully submitted that neither Rephaeli nor WO 98/09603 disclose or suggest, *inter alia*, a plasma level of about 250 μM to about 800 μM to treat multiple myeloma.

Thus, the cited documents fail to disclose all of the elements of the claimed invention. Therefore, for at least this reason, the claims are not rendered obvious over Rephaeli or Rephaeli in view of WO 98/09603. Accordingly, it is respectfully requested that the rejections of claims under 35 U.S.C. § 103(a) be withdrawn.

The Double Patenting Rejections

The Examiner provisionally rejected claims 1, 3-4, 11, 13-14, 26-29 and 34-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 13 and 15 of copending Application No. 09/634,207 or unpatentable over claims 16-20 of copending Application No. 09/634,207 in view of Spiegelman et al. (U.S. Patent No. 6,552,055). Applicants respectfully traverse the rejection.

Applicant respectfully submits that the co-pending U.S. Application is not yet allowed, hence the provisional rejection is premature. In addition, Applicants respectfully disagree with the Examiner. However, in order to expedite the allowance of the instant claims, while not conceding the obviousness of any number of the pending claims over the claims of the '207 application claims, should the instant application be allowed after the allowance of the aforementioned co-pending application (Ser. No. 09/634,207), an appropriate terminal disclaimer will be filed in the instant application.

However, as it is believed that the instant claims are in condition for allowance, it is respectfully requested that this "provisional" double patent rejection be withdrawn from this application as suggested as by M.P.E.P. § 804, which recites that "[i]f a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

The Examiner provisionally rejected claims 1, 3-4, 11, 13-14, 26-29 and 34-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12-23 of copending Application No. 10/682,790 in view of Spiegelman et al. (U.S. Patent No. 6,552,055). Applicants respectfully traverse the rejection.

Applicant respectfully submits that the co-pending U.S. Application is not yet allowed, hence the provisional rejection is premature. Pursuant to M.P.E.P. § 804, "[i]f a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable

on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." It is Applicants belief that the instant claims are in condition for allowance. Thus, the Examiner is respectfully requested to withdraw this provisional obviousness-type double patenting rejection of the instant claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DENNIS A. CARSON ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6905

Date March 24, 2006 By Monique M. Perdok Shonka
Monique M. Perdok Shonka
Reg. No. 42,989

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24 day of March, 2006.

JONATHAN FERGUSON
Name

Signature